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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/461,402	06/05/1995	ANDREW H. CRAGG	94-P0273US02	6448

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EXAMINER	
SONNETT, KATHLEEN C	
ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	08/461,402	CRAGG ET AL.	
	Examiner	Art Unit	
	KATHLEEN SONNETT	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *96-106* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *96-106* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :12/26/1996,3/16/1999,4/30/2001,8/20/2004,10/20/2008,5/13/2009.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements (IDS) received by the office on 12/26/1996, 3/16/1999, 4/30/2001, 8/20/2004, 10/20/2008, and 5/13/2009 have been considered. As requested by Applicant, a signed and initialed copy of each of these IDS sheets has been attached to this office action. Any citations on the above listed sheets which have been lined through refer to foreign documents of which no translation has been provided. These citations have not been considered.

Claim Objections

2. Claims 102 and 104 are objected to because of the following informalities

a. Claim 102: there appears to be a typographical error in lines 3-4: “comprising and at least one female…”.

b. Claim 104: delete “one” from “second one distal stents” in line 8. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **Claims 102 and 103** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 102 includes the apparatus of claim 101, "further comprising and at least one female engaging portion". It appears that "and" is a typographical error. Also, claim 96, from which claim 102 ultimately depends, already introduces the female engaging portion (line 16) and therefore the wording of claim 102 regarding “further comprising”

is confusing. The claim should be changed to clarify that the female engaging portion already claimed in claim 96 is being further defined in claim 102.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. **Claims 96-99 and 101-103** are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (US 5,575,817) in view of Hillstead (US 4,856,516), Cottone, Jr. (US 5,549,663; "Cottone"), and Lassiter et al. (US 1,417,393; "Lassiter"). Martin discloses an apparatus for reinforcing a bifurcated lumen comprising a proximal stent (1) having a proximal and distal end, the proximal stent further having a proximal orifice at the proximal end to be located in and when expanded to be supported by a vascular vessel and at least one distal stent (2) having a proximal and distal end. The distal stent comprises a male engaging portion formed on the proximal end of the distal stent. The proximal stent has two transversely placed portions that extend from an intermediate portion to the distal end of the proximal stent to reinforce the bifurcated lumen. These portions appear to have a slight taper in fig. 4. The proximal stent has a distal orifice at the distal end of at least one of the tapering portions which, when expanded, serves to receive the male engaging portion of the at least one distal stent. The proximal stent and the at least one distal stent each comprise an expandable stent constructed with a wire skeleton having one or more parts that extends from the proximal to the distal ends. The cross sectional area (CSA) of the proximal end of the distal stent (2) is larger than the CSA of the distal orifice of the proximal stent so as to partially secure together the stents when the distal

stent is expanded within the proximal stent (col. 3, ll. 29-36). Although Martin appears to show a slight tapering of the proximal and distal stents near their connection (see fig. 4), it is unclear where this tapering begins and ends and no mention of it is made in the text. Therefore, Martin does not expressly disclose that the male engaging portion has a frustoconical configuration that flares outward from the proximal end of an elongate cylinder extending from a medial portion to the distal end of the distal stent. Martin also fails to disclose the claimed structure of the stent regarding the hoops comprising a sinuous wire.

7. Hillstead teaches constructing a stent such that it comprises a plurality of hoops which are axially displaced in a tubular configuration along a common axis, each of the hoops being formed by a substantially complete turn of a sinuous wire having apices and having a circumference that lies in a plane substantially perpendicular to the longitudinal axis of the stent. It would have been obvious to incorporate this stent structure into the stents of Martin in order to gain the advantages associated with this structure including a high degree of flexibility and a more direct and uniform application of expansion forces to the stent (see entire document, esp. col. 2, ll. 14-25). Hillstead fails to disclose that the apices of adjacent hoops are juxtaposed to one another and at least two juxtaposed apices are connected by a securing means. Cottone teaches providing wire hoops which are out of phase such that apices of adjacent hoops are juxtaposed to one another and are connected by a securing means (weld point 18). These securing means are advantageous because, when applied at least to end portions of the stent, they provide anchoring portions within the stent which possess greater hoop strength than un-welded end portions, thereby making less likely unintentional movement of the stent after deployment (col. 1, ll. 20-24; col. 4, ll. 48-64). It would have been obvious to incorporate such a securing means as taught by Cottone into the device of Martin in view of Hillstead so that it too may have this advantage.

8. Lassiter discloses another apparatus comprising tubular elements joined together to form a fluid flow path which includes a tube comprising a male engaging portion having a frustoconical configuration that flares outward on the proximal end from an elongate cylinder. The second tube includes a distal orifice at a distal end (37) of a tapering portion (fig. 15; near 38). The tapering portion forms a female engaging portion that receives the frustoconically shaped male engaging portion completely within the female engaging portion. Lassiter teaches that the use of a tapering female engaging portion and frustoconical male engaging portion formed at the end of a cylindrical tube is advantageous because it allows a mechanical interlock to be provided between the two tubes which reinforces the connection between the two tubes and tends to prevent possible separation of parts under strains and thus adds to the security of the connection (page 3, ll. 93-113). It would have been obvious to one skilled in the art to have modified the device of Martin to include a male engaging portion having a frustoconical configuration that flares outward on the proximal end from an elongate cylinder extending from a medial portion to the distal end of the at least one distal stent in order to reinforce the friction-fit connection formed between the two stents. It is noted that it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the prior art of Lassiter is reasonably pertinent to the particular problem of forming a reliable, secure connection between the male and female connecting portions of two fluid carrying conduits.

9. Regarding claims 97 and 98, the proximal stent of Martin can be considered to have two intermediate portions, each of which are tapered as shown in fig. 4 of Martin and further taught by Lassiter to form distal portions with distal orifices. One of these tapered portions can be

considered the relatively short inclined extension that enables the distal stent to be located therein and secured thereto when the short extension has been expanded.

10. Regarding claim 99, see platinum wire (12) of Martin.

11. Regarding claim 101, the proximal and distal stents are configured for placement at a bifurcation. The proximal stent includes a lumen (within 5) that is configured to be disposed entirely within the vessel and is adapted to secure to the distal stent configured to extend into one of the two branched vessels.

12. Regarding claim 102, in figure 4 of Martin, the proximal portion of distal stent (2) and the distal portion (5) of proximal stent (1) are both tapered and form frustoconical shapes which are interference fit together. As discussed above, Martin does not expressly disclose that the male engaging portion is attached to the end of a cylinder since Martin does not disclose where the tapering of the stents begins or ends. Lassiter makes obvious providing the flared male engaging portion only on the distal end of the stent such that the remainder of the stent comprises a cylinder and the male engaging portion is received completely within the tapered, frustoconically shaped female engaging portion for inter-engagement between the outer surface of the male engaging portion and the inner surface of the female engaging portion. Each of these portions comprises a stent made of a wire skeleton since the entire device is made from such a skeleton covered with graft material.

13. Regarding claim 103, the distal stent has a fabric layer covering its outer surface. Since the proximal end of the distal stent is placed within the distal end of the proximal stent, the fabric layer will be between the male and female portions. This will form a substantially fluid-tight seal since the male and female portions are interference fit.

14. **Claim 100** is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin ‘817 in view of Hillstead, Cottone, and Lassiter as applied to claim 96 above and further in view of

Liebig (US 3,805,301). Martin '817 in view of Hillstead, Cottone, and Lassiter discloses the invention substantially as stated above including radiographic indicia on the proximal and distal stents (wire 12). The wire of Martin '817 goes around the entire circumference of the stents and therefore the image of the radiopaque markers will not vary with the rotational orientation of the stent. However, Liebig teaches that it is well known to provide markers along the longitudinal axis of a stent such that the rotational orientation affects the shape of the marker (see abstract). In particular, if the graft is twisted at all, the marker will be twisted. It would have been obvious to attach the wire of Martin '817 in a longitudinal manner as taught by Liebig so that any twisting of the graft structure can be easily determined by viewing the marker. With this modification, the radiographic image of the radiographic indicia varies with rotational orientation of the stent.

15. **Claims 104 and 106** are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (US 5,653,743; "Martin '743") in view of Hillstead, Cottone, and Lassiter. Martin '743 discloses an apparatus (1) for reinforcing a bifurcated lumen comprising a proximal stent having a proximal end and a distal end, the proximal stent being expandable and having a proximal orifice at the proximal end. Martin further discloses first and second distal stents (fig. 5 shows one of them) each having a proximal and distal end comprising an engaging portion (see "18" in fig. 5; col. 4, ll. 15-21 which discloses treating the internal iliac artery too, formerly known as the hypogastric artery). The proximal stent has two transversely placed portions that extend from an intermediate portion to the distal end of the proximal stent to reinforce the bifurcated lumen as shown in figure 1 (see also col. 3, ll. 4-5) . The proximal stent also has a distal orifice at the distal end of at least one of the transversely placed portions that, when expanded, receives the engaging portion of at least one proximal end of the first and second distal stents (fig. 5). The stents are expandable and constructed of a wire skeleton having one or more parts that extends from the respective proximal ends to the distal ends. Martin fails to disclose the claimed

structure of the hoops of the stent as well as the cross-sectional area (CSA). Martin '743 discloses that the proximal and distal stents overlap but is silent on which stent forms the male engaging portion and which stent forms the female engaging portion, as well as the claimed tapering of these regions.

16. Lassiter discloses another apparatus comprising tubular elements joined together in an overlapping fashion to form a fluid flow path. The apparatus includes a tube comprising a male engaging portion having a frustoconical configuration that flares outward on the proximal end from an elongate cylinder portion formed by the remainder of the tube. The male engaging portion is received completely within the tapered, female engaging portion of a second tube having two side-by-side outlets. A shown in fig. 15, the cross-sectional area (CSA) of the distal orifice of the proximal tube is smaller than the CSA of the proximal end of the distal tube so as to at least partially secure together the proximal and distal tubes. Lassiter teaches that a tapering female engaging portion and frustoconical male engaging portion formed at the end of a cylindrical tube is advantageous because it allows a mechanical interlock to be provided between the two tubes which reinforces the connection between the two tubes and tends to prevent possible separation of parts under strains and thus adds to the security of the connection (page 3, ll. 93-113). It would have been obvious to one skilled in the art to have modified the device of Martin ‘743 to include a male engaging portion having a frustoconical configuration that flares outward on the proximal end of the cylindrical distal stent and is completely received within the tapered, female engaging portion of the proximal stent in order to reinforce the friction-fit connection formed between the two stents.

17. Regarding the structure of the stents, Hillstead teaches constructing a stent such that it comprises a plurality of hoops which are axially displaced in a tubular configuration along a common axis, each of the hoops being formed by a substantially complete turn of a sinuous

wire having apices and having a circumference that lies in a plane substantially perpendicular to the longitudinal axis of the stent. It would have been obvious to incorporate this stent structure into the stents of Martin '743 in order to gain the advantages associated with this structure including a high degree of flexibility and a more direct and uniform application of expansion forces to the stent (see entire document, esp. col. 2, ll. 14-25). Hillstead fails to disclose that the apices of adjacent hoops are juxtaposed to one another and at least two juxtaposed apices are connected by a securing means. Cottone teaches providing wire hoops which are out of phase such that apices of adjacent hoops are juxtaposed to one another and are connected by a securing means (weld point 18). These securing means are advantageous because, when applied at least to end portions of the stent, they provide anchoring portions within the stent which possess greater hoop strength than un-welded end portions, thereby making less likely unintentional movement of the stent after deployment (col. 1, ll. 20-24; col. 4, ll. 48-64). It would have been obvious to incorporate such a securing means as taught by Cottone into the device of Martin '743 in view of Hillstead so that it too may have this advantage.

18. Regarding claim 106, it would have been obvious to apply the teaching of Lassiter regarding the distal stent having a larger CSA than the proximal stent's orifice in which it is seated to both distal stents so that they are both interference fit with the proximal stent.

19. **Claim 105** is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin '743 in view of Hillstead, Cottone, and Lassiter as applied to claim 104 above and further in view of Chuter (US 5,562,726). Martin '743 in view of Hillstead, Cottone, and Lassiter discloses the invention substantially but does not disclose securing the proximal and distal stents with suture. However, Chuter discloses that it is well known to use suture to attach distal graft legs to a bifurcated proximal graft (see figs. 28 and 29). It would have been obvious to one skilled in the art to have further modified Martin '743 to include securing the proximal and distal stents with

suture as taught by Chuter to provide additional means of preventing the stents and graft material from separating.

Response to Arguments

20. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendments.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 5/20/2011
/Kathleen Sonnett/
Primary Examiner, Art Unit 3731